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#9

March 24, 1989

Mr. Ronald Wilson  
Office of the Associate Commissioner  
for Health Affairs (HFY-20)  
Room 11-46  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

RE: Hismanal  
FDA Docket # 89E-0085

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for Patent Term Extension of U.S. Patent No. 4,219,559 issued August 26, 1980. The application was filed on February 10, 1989 under 35 U.S.C. § 156.

The patent claims a product and process of using a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary.

Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A) for a determination of the length of the regulatory review period.

*C. E. Van Horn*

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Charles E. Van Horn  
Deputy Solicitor  
Patent and Trademark Office

cc: Robert L. Minier  
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